

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
CENTRAL DIVISION**

ABBOTT GMBH & CO., KG; and ABBOTT
BIORESEARCH CENTER, INC.

Plaintiffs,

v.

CENTOCOR ORTHO BIOTECH, INC.

Defendant.

Civil Action No. 4:09-cv-11340-FDH

Jury Trial Demanded

**DEFENDANT'S PRELIMINARY INVALIDITY AND NON-INFRINGEMENT
CONTENTIONS**

Pursuant to Local Rules 16.1 and 16.6 and the March 2, 2010 Initial Scheduling Order (modified by May 27, 2010 order), Defendant Centocor Ortho Biotech, Inc. (“Centocor”) hereby makes the following Preliminary Invalidity and Non-Infringement Contentions.

Discovery has just begun, and the Preliminary Contentions herein are based on information and documents currently available to Centocor. Centocor reserves the right to amend and/or supplement these Preliminary Contentions, including as set forth by the March 2, 2010 Scheduling Order. Centocor also reserves the right to rely on additional evidence to support its Preliminary Contentions.

I. Preliminary Invalidity Contentions

A. Obviousness

Each of the asserted claims of U.S. Patent No. 6,914,128 (the “128 patent”) and U.S. Patent No. 7,504,485 (the “485 patent”) are obvious in light of at least the following, alone or in combination:

U.S. Patent No. 5,569,825 (Lonberg et al.)
U.S. Patent No. 5,545,806 (Lonberg et al.)
U.S. Patent No. 5,545,807 (Surani et al.)
U.S. Patent No. 5,625,126 (Lonberg et al.)
U.S. Patent No. 5,633,425 (Lonberg et al.)
U.S. Patent No. 5,661,016 (Lonberg et al.)
U.S. Patent No. 5,770,429 (Lonberg et al.)
U.S. Patent No. 5,789,650 (Lonberg et al.)
U.S. Patent No. 5,814,318 (Lonberg et al.)
U.S. Patent No. 6,300,129 (Lonberg et al.)

U.S. Patent No. 6,255,458 (Lonberg et al.)
U.S. Patent No. 7,084,260 (Lonberg et al.)
U.S. Patent No. 5,530,101 (Queen et al.)
U.S. Patent No. 5,652,138 (Burton et al.)
U.S. Patent No. 5,804,440 (Burton et al.)
U.S. Patent No. 5,910,486 (Curiel et al.)
U.S. Patent No. 5,780,597 (Gately et al.)
U.S. Patent No. 6,225,117 (Gately et al.)
U.S. Patent No. 5,811,523 (Trinchieri et al.)
U.S. Patent No. 6,284,471 (Le et al.)
U.S. Patent No. 5,919,452 (Le et al.)
U.S. Patent No. 5,656,272 (Le et al.)
U.S. Patent No. 5,698,195 (Le et al.)
U.S. Patent No. 6,277,969 (Le et al.)
U.S. Patent No. 6,054,487 (Sekut et al.)
U.S. Patent No. 6,090,382 (Salfeld et al.)
U.S. Patent No. 6,258,562 (Salfeld et al.)
U.S. Patent No. 5,654,407 (Boyle et al.)
U.S. Patent No. 6,150,584 (Kucherlapati et al.)
U.S. Patent No. 6,673,986 (Kucherlapati et al.)
PCT Publication WO90/05144 (Winter et al.)
PCT Publication WO92/01047 (McCafferty et al.)
PCT Publication WO93/11236 (Griffiths et al.)

PCT Publication WO93/06213 (Hoogenboom et al.)
PCT Publication WO98/50433 (Jakobovits et al.)
PCT Publication WO98/24893 (Jakobovits et al.)
PCT Publication WO98/41232 (Sekut et al.)
PCT Publication WO98/24884 (Lonberg et al.)
PCT Publication WO97/13852 (Lonberg et al.)
PCT Publication WO94/25585 (Lonberg et al.)
PCT Publication WO94/002602 (Kucherlapati et al.)
PCT Publication WO96/33735 (Kucherlapati et al.)
PCT Publication WO96/34096 (Kucherlapati et al.)
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McCafferty et al., Nature 348:552 (1990)
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Kang et al., PNAS 88:4363 (1991)
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Hanes et al., PNAS 94:4937 (1997)
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Meager et al., Lancet 350, 1596 (1997)
Bruggemann et al., Curr. Op. Biotechnol.. 8:455 (1997)
Rader et al., Curr. Op. Biotechnol. 8:503 (1997)
Eren et al., Immunol. 93:154 (1998)
Katsube et al., Int. J. Mol. Med. 1:863 (1998)
Hanes et al., PNAS 95:14130 (1998)
Beeson et al., Ann. NY Acad. Sci. 841:371 (1998)
Sheets et al., PNAS 95:6157 (1998)

B. Prior Invention

Centocor employees are the prior inventors of the asserted claims of the 128 and 485 patents pursuant to 35 U.S.C. § 102(g)(2). Centocor employees conceived and reduced to practice the alleged invention set forth in the asserted claims prior to the filing dates of the 128 and 485 patents and prior to any earlier date that Abbott may properly rely on for priority, including for the reason that the Abbott inventors abandoned, suppressed, and/or concealed their alleged invention.

C. Indefiniteness

Claims 1-15, 27-40, 50-64, and 70 of the 128 patent and claims 11 and 24 of the 485 patent are invalid for failing comply with the requirement of 35 U.S.C. § 112 to particularly point out and distinctly claim the subject matter which the applicant regards as his invention. Each of those claims recites kinetic properties, including K_d 's and/or rate constants, the values of which depend on the testing methods and conditions used. Those testing methods and conditions are not adequately set forth in those claims, so that a person of ordinary skill cannot determine the metes and bounds of those claims.

Claims 8-15, 33-40, and 53-63 of the 128 patent and claims 10 and 26 of the 485 patent are invalid for failing comply with the requirement of 35 U.S.C. § 112 to particularly point out and distinctly claim the subject matter which the applicant regards as his invention. Each of those claims recites biological properties, including IC_{50} 's, the values of which depend on the testing methods and conditions used. Those testing methods and conditions are not adequately set forth in those claims, so that a person of ordinary skill cannot determine the metes and bounds of those claims.

D. Lack of Written Description

Claims 1-15, 27-40, 50-64, and 70 of the 128 patent and claims 11 and 24 of the 485 patent are invalid for failing to meet the written description requirement. The specifications of the 128 and 485 patents do not describe an antibody that meets the limitations of those claims so that a person of ordinary skill would understand that the inventors were in a possession of such an antibody, because the specifications do not describe an antibody tested by a reliable method for determining rate constants and/or K_d 's.

Each of the asserted claims is invalid for failing to meet the written description requirement because the specifications do not evidence that the inventors were in possession of the entire genus of antibodies claimed.

E. Lack of Enablement

Claims 1-15, 27-40, 50-64, and 70 of the 128 patent and claims 11 and 24 of the 485 patent are invalid for failing to meet the enablement requirement. The specifications of the 128 and 485 patents do not enable the person of ordinary skill to make an antibody that meets the limitations of those claims, because the specifications do not teach a reliable method for determining rate constants and/or K_d 's.

Each of the asserted claims is invalid for failing to meet the enablement requirement because the specifications do not provide sufficient description to enable one skilled in the art to make the full scope of the invention as claimed.

II. Preliminary Non-Infringement Contentions

Centocor does not infringe any of the asserted claims, because the accused product Stelara™ does not contain each and every limitation of the asserted claims either literally or under the doctrine of equivalents.

For example, the accused product does not meet the K_d or rate constant elements set forth in claims 1-15, 27-40, 50-64, and 70 of the 128 patent and claims 11 and 24 of the 485 patent.

As an additional example, the accused product does not meet the IC_{50} elements set forth in claims 8-15, 33-40, and 53-63 of the 128 patent and claims 10 and 26 of the 485 patent..

As an additional example, the accused product does not comprise an additional agent as set forth in claims 1-4, 6-11, 15-19, and 24-26 of the 485 patent.

Date: June 7, 2010

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CERTIFICATE OF SERVICE

I certify that, on June 7, 2010, this document (filed through the ECF system) will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

/s/ Matthew A. Pearson